A Monsanto case that could alter the dynamics of technology transfer to India

Darren Smyth Friday, March 04, 2016 - competition law, compulsory licences, crop resistance, india, monsanto

The IPKat is delighted to receive this guest post from long time Katfriend and sometime blogger Prashant Reddy (details at the end of the post).

For the last several months Monsanto and Indian seed companies, backed by the Indian government (& state governments) have been locked in a wide-ranging legal dispute over the use of price-control legislation to fix IP licensing fees, the demand for compulsory licences for Monsanto's patent over its Bt technology, demands by state governments for the outright revocation of Monsanto's patent over its Bt technology, and an ongoing investigation into Monsanto's licensing deals.

Before explaining the legal dispute, it may help to first understand the technology involved along with the licensing model adopted by Monsanto in India.

The technology, the patent and the business model

The technology in this case is Monsanto's famous Bt technology, which involves the introgression of certain genes of *Bacillus thurgingiensis* (Bt), a naturally occurring bacteria, into the genome of cotton seeds in order to ensure the resulting crop's resistance to certain pests of the lepidopteran species. In specific, Monsanto's technology is known to act against the Bollworm which is the most atrocious of pests that attacks and destroys the cotton crop. The use of this technology reduces or maybe in some cases even eliminates the pesticides that are required to be used by farmers.

A cotton bollworm larva

Although the first generation of Bt technology, was never patented by Monsanto in India, the second generation Bt technology licensed under the trademark Bollguard-II variety ® is patented. Monsanto was granted Indian patent 232681 (drawing priority from US 60/297,406) on March 20, 2009 for the "Cotton event Mon 15985 and compositions and methods for detection". Claim 1 of this patent is for a synthetic DNA molecule, comprising a particular genetic sequence consisting of selected Bt genes which are inserted into the genome of cotton seeds.

As per the entries in the patent register, Monsanto has licensed this patent to its joint-venture in India called the Mahyco Monsanto Biotech (India) Ltd. which has in turn entered into sub-licences with approximately 40 Indian seed companies. These seed companies evolve their own seed varieties, which can be protected under the Protection of Plant Varieties & Farmers Rights Act, 2001 and these seeds are then introgressed with Monsanto's patented gene technology. Monsanto is paid a royalty for the patented technology, know-how etc. As per Monsanto's filing with the Patent Office in 2013, it earned an annual revenue of 6.85 billion rupees in that year (Approx. US $110 million dollars in 2013).

Price control over technology licensing fees

A constant complaint against Monsanto from the very beginning has been that its technology licensing fees for Indian seed companies are too high, thereby raising prices for the cotton seeds that are sold to farmers. About a decade ago, Indian state governments successfully applied pressure on Monsanto to reduce the technology licensing fees for its unpatented BG-1 technology. This happened at a time when Monsanto didn't have any patents in India for its technology.

Over the last few years, the pricing issue has once again come back into focus. This time state governments enacted legislation to control the retail prices of seeds but most have not interfered with the technology license fee charged by Monsanto to seed companies. The Indian seed companies felt the pinch of the price control legislation because, while the states were reducing the retail price of cotton seeds, Monsanto was refusing to reduce its technology licensing fee. Thus the margins of the seed companies were getting squeezed.

All of this changed in December 2015 when the Ministry of Agriculture of Government of India notified the Cotton Seeds Price (Control) Order (CSPO), 2015. This Order derives its authority from the Essential Commodities Act, 1955 – legislation which vests in the government powers to control the prices of a wide range of essential commodities such as drugs, food crops, sugar, foodstuffs etc. for the purpose of securing the "equitable distribution and availability of these commodities at fair prices or for maintaining or increasing supplies of the same". This legislation is usually used to control the retail price of the commodity in the market. To the best of my knowledge, this legislation has never been used to control the royalty or licensing fee for the use of a patent or technology transfer. Even in the context of drugs, the Drug Price Control Order (DPCO) has always covered only generic drugs despite calls for it to be extended to patented drugs.

The CSPO however makes it expressly clear that while the Government is fixing the maximum retail price of cotton seeds, "it shall also fix and regulate the seed value and license fee including royalty or trait value, if any, that constitute components of the Maximum Sale Price". The phrase "royalty (trait value)" is defined in the Order as "the amount which the Licensor collects from the Licensee under the License Agreement for granting licence to GM Technology". Technically this could include even the royalties for know-how or trade secrets not covered by patent. The phrase "GM Technology" itself is defined in the CSPO to specifically include Bt technology.

The interesting question of law thrown up by this case is whether the Essential Commodities Act can be used by the Government of India to control the royalty fees in patented technology when the Patents Act, 1970 specifically provides for a mechanism, involving compulsory licences, to help reduce the prices of patented technologies if it is in public interest. Monsanto and its Indian subsidiaries have already challenged this order before the Delhi High Court and the determination of this dispute by the Delhi High Court will have a direct implication on the price control of patented pharmaceuticals – which is a far more explosive an issue than cotton seeds. The larger implication of course is on future technology licensing deals with Indian parties. Any decision by the Delhi High Court to uphold the CPSO would mean that the Government of India, and in some cases even State Governments, could intervene to regulate technology licensing fees between two private parties.

The demand to issue compulsory licences

Earlier this month, the Indian media had reported that the Government of Andhra Pradesh, a major cotton growing state in South India (& home to the largest Indian seed companies), has written to the Government of India asking it to invoke its powers under Section 92 of the Patents Act to issue compulsory licences for Monsanto's patent on the grounds that "Monsanto is having a monopoly and through one-sided sub-licence agreements is completely controlling all the cotton seed firms and, thereby, collecting excessive royalties". Section 92 is a provision which states that the Central Government may in cases of a national emergency or in case of extreme urgency or in case of public non-commercial use, make a declaration that a certain patent will be available for compulsory licensing. This provision is different from Section 84, under which Bayer's patent was compulsory licensed to Natco, an Indian company. Under Section 84, the burden of proof is on the person seeking a CL and it is not easy to establish the threshold for the grant of a CL. This threshold includes unreasonable prices, unavailability of the patented commodity etc. However under Section 92, once the govt. makes a determination that a CL needs to be granted, third parties are relieved of the burden of establishing the threshold required under Section 84. They are then only required to make an application the Controller of Patents who is required to grant a compulsory licence on certain terms and conditions determined by him.

In 2013, the Central Government was seriously considering the possibility of invoking Section 92 for 3 cancer drugs: Herceptin, Dastinib and Ixabepilone. The Indian Government never went through with the threat and no CLs were ever issued. Whether the Government of India acts on this request from the Government of Andhra Pradesh remains to be seen.

Revocation request under Section 66

The Government of Andhra Pradesh has apparently also requested the Government of India to revoke Monsanto's patent under Section 66 of the Patents Act. This is a provision which allows the Central Government to revoke patents in 'public interest' if the Government is of the opinion that "a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public". The patentee is given a hearing after which the Government is only required to publish a declaration in the Official Gazette revoking the patent. This provision has been used twice in the past. The first such revocation was in 1994, of a patent granted to Agracetus, for a method to genetically modify cotton cells. The second such revocation, in 2013, was of a patent belonging to Indian company Avesthagen because it allegedly claimed traditional knowledge. The Traditional Knowledge Digital Library (TKDL) had challenged the European equivalent of the patent (which had in any case been objected to by the EPO) but had not opposed the equivalent Indian patent. Once this was reported on SpicyIP, the Indian Government used its powers under Section 66 to revoke the patent. It is quite unlikely that the Government of India will use these powers under Section 66 because the provision isn't exactly TRIPS compliant and any action under this provision is likely to stir controversy on the international stage.

The lawsuits before the Bombay and Delhi High Courts & the inevitable question on gene patents

Since late last year there has been a virtual explosion of litigation between MMBL and the Indian seed companies. The first series of litigation kicked of last year after 8 of the largest Indian seed companies refused to pay MMBL outstanding royalties of approximately four billion rupees. The refusal was triggered by the fact that state governments were clamping down on the retail prices of cotton seeds under price control legislation and MMBL was refusing to reduce its technology licensing fee. As a result the Indian seed companies were faced with squeezed margins. In retaliation to the non-payment of royalties, MMBL terminated the licensing agreements, initiated arbitration proceedings before the Bombay High Court and infringement proceedings before the Delhi High Court. As per recent reports, Monsanto and its group companies have instituted trademark infringement proceedings before the Delhi High Court against Nuziveedu Seeds Ltd. The court order is unavailable but according to the news reports the court passed interim orders restraining Nuziveedu from selling the seeds manufactured after November 2015 and the company was also ordered to pay Monsanto the royalties on the existing stock. It isn't clear how the High Court issued such interim orders for damages before trial. Due to a new law governing commercial litigation in India, such interim orders cannot be appealed – only final judgments can be appealed.

Also inevitable in this series of litigation is a challenge to Monsanto's patent – to the best of my knowledge, gene patents have never been litigated in India. If Nunziveedu Seeds Ltd. decides to challenge the validity of Monsanto's patent any resulting litigation will be high-profile because Monsanto is one of those companies that everybody loves to hate in India.

The Competition Commission investigation

In addition to all of the above, the Competition Commission of India (CCI) has recently ordered an investigation into MMBL's licensing deals, after receiving a reference from the Ministry of Agriculture and a separate complaint from Nuziveedu Seeds Ltd. MMBL is Monsanto India's JV which licences the patent in question from Monsanto Technology LLC (USA) and then in turn sub-licences the technology to over 40 Indian seed companies.

The procedure before the CCI is two-fold. At the first stage, the CCI determines whether there exists a *prima facie* case of violation of the Competition Act and if it does make such a determination, an investigation will be conducted by the Director General's office, after which a hearing is conducted on the merits and a ruling is delivered. If no *prima facie* case is made out the complaint is dismissed.

In this particular case, the CCI has found that MMBL is *prima facie* in a dominant position in the relevant product market (identified as the provision of Bt cotton technology in the upstream and manufacture and sale of Bt cotton seeds in India in the downstream) and the relevant geographical area (identified as the entire country of India). While there is no denying that MMBL has virtually 99% of the market share, the issue of dominance should be judged by the ability of MMBL to operate independently of competitive forces prevailing in the market. In other words, if the market offers alternatives whereby the downstream player is able to substitute MMBL's technology or survive without MMBL's technology, the company should not be found to be the dominant player.

In this case, it is entirely possible to manufacture cotton seeds without Bt technology, except the farmers planting these seeds will have to use pesticides to tackle the Boll Worm. Prior to 2001, Indian farmers were growing cotton without the Bt technology. MMBL's technology is therefore substitutable. Further, even with regard to Bt technology, MMBL has been licensed a patent for only one particular gene sequence – its competitors can still use the old Bt technology which is not patented or innovate to create new GM hybrids. In fact, recent news reports indicate that the publicly funded Central Institute for Cotton Research (CICR) has begun field trials with 21 different varieties of cotton seeds which have been introgressed with Bt technology. In either case, the CCI should have interpreted the scope of MMBL's patent and analysed whether competitors were completely precluded from entering the market. Unfortunately there is no such discussion in the order.

After finding that MMBL had a dominant position, the CCI also found that the company was abusing its dominant position because the termination conditions imposed by MMBL in its licences were allegedly unreasonable and beyond what was required to legitimately protect its IP rights. One of the termination conditions imposed a requirement to inform MMBL within 30 days if the licensee was developing hybrid cotton seeds with technology derived from MMBL's competitors. Other conditions required that once a termination notice was served, the licensee immediately stop selling the seeds in question followed by destroying the seeds in existence and also destroying all the parent lines. An additional condition allowed MMBL to terminate the sub-licence if any law was enacted to restrict the technology licensing fee. The CCI also accepted the allegation that MMBL may have terminated the licenses with the informant in order to protect its presence in the downstream market i.e. the seed markets in which its group companies were involved. The imposition of such restrictive conditions along with the suspicion that MMBL was influencing the downstream market through its group companies led to a preliminary, prima facie finding of abuse of Monsanto's dominant position.

Once again, the above reasoning isn't clear. The termination conditions which the CCI finds to be an 'abuse' are basically the boiler-plate clauses in any technology transfer contract and are the industry standard. Further the allegation that MMBL was terminating the licenses of companies like Nuziveedu just to protect its group companies isn't really tenable – the 8 sub-licenses were terminated by MMBL because of non-payment. Besides, there are approximately 32 other sub-licensees for the technology – so there is considerable competition in the downstream market. Unfortunately, the CCI's analysis does not cover any of these issues. Hopefully the investigation by the Director General will bring out these points in more detail.

In addition to the preliminary finding of abuse of dominant position, the CCI also made a preliminary finding that the licensing agreements were themselves anti-competitive in nature because of the stringent termination conditions discussed above. In the Commission's words "The termination conditions are found to be excessively harsh and do not appear to be reasonable as may be necessary for protecting any of the IPR rights, as envisaged under Section 3(5) of the Act. Such agreements discourage and serve as a major deterrent for the sub licensee from exploring dealing with competitors." This reasoning is simply not convincing because such conditions are part and parcel of any tech-transfer deal. Hopefully the investigation by the Director General will do a better job.

Notwithstanding that the CCI's findings are only preliminary – MMBL's stock tanked 4% after the announcement of the investigation. The manner in which the Indian judiciary and regulators deal with the issues raised in this case is going to have a profound influence on the manner in which technology is transferred to Indian companies in the future.

For a bit of history on this post, do read my earlier post on SpicyIP over here.

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